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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/027,671	02/23/1998	ALAN K. SMITH	4292-0048-55	3507

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EXAMINER

SAUNDERS, DAVID A

ART UNIT PAPER NUMBER

1644

DATE MAILED: 06/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/027,671

Applicant(s)

SMITH ET AL.

Examiner

David A. Saunders, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 70-94 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 70-94 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

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Amendment of 3/13/06 has been entered. Claims 70-94 are pending. Claims 70-94 are under examination. The amendment has entered no new matter.

The amendment has overcome previously stated issues as follows:

The objection to claim 41 under 37 CFR 1.75.

The rejection of claims 6-7,10-12,38-41,49-58 and 60-66 under 35 USC 112, 2nd paragraph, due to their cancellation.

The rejection of claims 6-7,10-12,38-41,49-58 and 60-66 under 35 USC 112, 1st paragraph, due to their cancellation.

The obviousness-type double patenting rejection, due to the filing of an accepted terminal disclaimer.

The following rejections of record are maintained or modified as follows:

Claims 70 and 73 are rejected under 35 U.S.C. 102(b) as being anticipated by Emerson et al (US '994, '822, '386, '043, '147 or '198) for reasons of record.

Applicant has urged that the culturing conditions (e.g. the media used) of Emerson et al are not those that would enable "mature, terminally differentiated cells to expand and attain enhanced biological function as claimed." The examiner firstly notes that applicant's claims do not require the "mature, terminally differentiated cells" to "expand". Rather, the claim merely requires that the enable "mature, terminally differentiated cells" attain "enhanced biological function". The only claim that requires that there be any enhanced capacity for the cultured cells to "expand" is dependent claim 75, which requires the cultured cells to have "enhanced replicative potential."

As previously noted, while the teachings of Emerson et al appear, on the surface, to relate to the culturing of hematopoietic stem cells and/or hematopoietic progenitor cells, rather than mature hematopoietic cells, one must consider the teachings to their full extent, and one must interpret the claims as they can be interpreted to their broadest reasonable extent. It is noted that Emerson et al teach that their rapidly exchanged cultures included a population of nonadherent cells; this population of nonadherent cells included erythroid cells, late granulocytes, and macrophages; each of these cell types

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were produced in percentage amounts that varied with the week of culturing and with the combination of HGFs employed. See '043 at col. 26, line 60-col. 27, line 18.

As far as the examiner can tell from the all embracing nature of applicant's disclosure, the erythroid cells, granulocytes/late granulocytes, and macrophages are properly deemed to be "mature" cells of hematopoietic lineage. It is not clear to the examiner how these cells, especially the "late granulocytes" are to be considered different from what applicant deems to be "mature, terminally differentiated cells" of new claim 70. It is noted that "comprising" in instant claim 70 permits the claim scope to include the culturing of hematopoietic stem cells and/or hematopoietic progenitor cells, along with "mature" hematopoietic cells, such as erythroid cells, late granulocytes, and macrophages. Emerson et al are thus culturing the same type of cells as applicant.

The examiner further finds applicant's urgings that Emerson et al do not teach the appropriate "types of culture conditions (e.g. media)" to obtain the instant mature cells to be off point. Claim 70 does not require any particular type of culture media; rather, the claim merely requires that the media be exchanged. Dependent claim 74 does require that the culture medium contain "at least one growth factor which stimulates proliferation" but recites no particular factors. Emerson et al did, in fact, add growth factors such as G-CSF and GM-CSF to the cultures taught at cols. 26-27; see col. 2, lines 14-17 referring to these as examples of "growth factors". To the extent that any of these may enhance the proliferation of "mature, terminally differentiated hematopoietic cells", instant claim 74 must be considered anticipated.

Applicant has also urged that the "mature" cells of Emerson et al are "depleted and not growing", by reference to col. 5, lines 34-40 of the '043 patent. The examiner finds nothing at col. 5, lines 34-40 that indicates anything about the mature cells being "depleted and not growing". Likewise, the examiner finds nothing at cols. 26-27 that indicates that the mature cells, in the nonadherent fraction, were "depleted and not growing". While there appear to be some indications that the production rates of these mature cells may have fallen off, after 18 weeks (see '043 at col. 27, lines 7+), this teaching does not negate anticipation. As long as there was an enhanced

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production/differentiation of these mature cells at any time over the course of the culturing conditions of Emerson et al, claim 70 is anticipated.

Applicant has urged that the '043 patent teaches at col. 5, the removal of mature cells from the culture by immunological techniques; applicant has urged that the '822 patent teaches likewise. This section at col. 5 of the '043 patent merely tells one how to separate out the mature cells from a culture for the case in which one would desire to recover the hematopoietic stem cells or the hematopoietic progenitor cells free of mature cells. It is to be noted that, in the experiments involving exchange of the culture media, Emerson et al were careful to retain the mature cells in the nonadherent cell fraction when the cell culture medium was replaced. These nonadherent cells were recovered from the old medium by centrifugation and returned to the culture along with the fresh medium; see col. 20, lines 42-54. Thus mature cells in the nonadherent fraction were, in fact, not separated out but, rather, were recovered and placed back in the culture.

Applicant's arguments filed 3//13/06 have been fully considered but they are not persuasive for the above reasons.

Applicant's amendment has necessitated the following new ground(s) of objection/rejection.

Claim 70 is objected to because of the following informalities: In claim 70, line 2, it is considered that a comma is intended between "mature" and "terminally". Appropriate correction is required.

Claims 70-94 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 70, 73 and 75-94 the term "mature, terminally differentiated human hematopoietic cells" is confusing. The phrase is self-contradicting because the term "hematopoietic" refers to the "formation of blood cells"; see Dorland's Illustrated Medical Dictionary at page 742. Since "terminally differentiated" cells are at an end stage

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and would not be involved in the “formation” of any other kinds of more differentiated cells, it is not understood how any “hematopoietic cells” can be considered as “terminally differentiated”.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, PhD whose telephone number is 571-272-0849. The examiner can normally be reached on Mon.-Thu. from 8:00 am to 5:30 pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you

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have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Typed 6/10/06 DAS

David A Saunders

DAVID SAUNDERS
PRIMARY EXAMINER

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